

K062107

510(k) Summary SecurView DX

AUG 18 2006

Product Name: SecurView DX

Product Classification Name: Picture archiving and communication system

Product Classification Code: LLZ CFR Section: 892.2050

Classification Panel: Radiology **Class II**

Manufacturer: Hologic, Inc.
36 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Gail Yaeker-Daunis
Telephone Number: (203) 731-8337
Fax Number: (203) 731-8440

Date Prepared: July 18, 2006

Predicate Device: K041555 SecurView DX, Hologic Inc.

Device Description: The Hologic SecurView DX is mainly a software product. It is used for visualization and manipulation of digital radiology images. The SecurView DX is a multi-modality review workstation software focused on mammographic applications. The software can drive at least two high-resolution gray scale displays (FDA cleared for Mammography), a PC mouse, a keyboard and an optional dedicated workflow keypad.

The software accepts standard or multi-frame mammography images that have been created according to the “FOR PRESENTATION” specification of the DICOM Standard with no compression or using lossless compression. Image processing is external to the SecurView DX software.

The software accepts multimodality images of US, MR, DR, CR, SC, CT, PET, and other DICOM formats for display and manipulation on the high resolution 5 MP gray scale displays or on a color 2 MP display in 2-D or 3-D view.

The SecurView DX software can be used in a single or in a multi-workstation configuration.

The minimum computer requirements to run the SecurView DX software are:

Windows XP® Operating System

Intel CPU with a clock rate of 2.0 GHz or greater

2.0 GB RAM or greater

140 GB Hard drive or greater, operating at 160 Mbs or greater

CD-ROM/R
10/100 Base TX Network Interface

Intended Use:

The Hologic SecurView DX is intended for selection, display, manipulation, filming and media interchange of multi-modality images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or similar interface standards.

The device may be used by a trained physician for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images using FDA cleared displays for screening and diagnostic mammography, as well as any other DICOM multi-modality image.

The SecurView DX software is typically used by trained professionals, including, but not limited to physicians, radiologists, nurses, medical technicians and assistants.

Comparison with Predicate Device:

The modified SecurView DX is substantially equivalent to the SecurView DX cleared August 9, 2004 as 510(k) #K041555 and has the same intended use as stated above.

SecurView DX (K)041555	SecurView DX Modified
Intel CPU with clock rate of 2.0 GHz or greater	Same
2.0 GB RAM or greater	Same
140 GB Hard drive or greater operating at 160 Mbs or greater	Same
CD ROM/read/write / DVD +/- read/write	CD ROM/R
Windows 2000 Operating System	Windows XP Operating System
US QWERTY Keyboard	Same
10/100 Base TX Network Interface	10/100 Base TX Network Interface
3-button Mouse	Pointing Device w/wheel
Workstation Keypad	Workstation Keypad
(2) High-Resolution Grey Scale Display (FDA cleared for Mammography) 21" Portrait Orientation, Resolution 2058/2560 pixels (5MP)	At least two High-Resolution Grey Scale Displays (FDA cleared for Mammography) Optional Color at least 2 MP, High Contrast Display for Multimodality viewer

SecurView DX (K)041555	SecurView DX Modified
Bar Code Reader (Code 39 Full ASCII, Code 128, Code 39)	Same

Software:

The SecurView DX software is specified, validated and tested by Hologic, Inc., under an ISO 13485 and 21 CFR Part 820 Quality System.

Safety and Effectiveness - Performance Standards:

The SecurView DX software is specified, validated and tested by Hologic, Inc., under a registered ISO 13485 and 21 CFR Part 820 Quality System.

The SecurView DX software complies with ACR/NEMA Digital Imaging Communications in Medicine version PS 3.1-3.18 (DICOM) Set

An Operator's Manual will be provided with each system that is user friendly and comprehensive, thus ensuring safe and effective operation.

Conclusion:

Similar to the predicate device, the SecurView DX software displays and manipulates DICOM images to be interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. The device and the predicate device share similar performance standards. Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use. Potential hazards have been studied and controlled by a Risk Management Plan. Based on the information supplied in this 510(k), Hologic concludes that the device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 18 2006

Ms. Gail Yeaker-Daunis
Senior Regulatory Specialist
Hologic, Inc.
36 Apple Ridge Rd.
DANBURY CT 06810

Re: K062107

Trade/Device Name: SecurView DX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 20, 2006
Received: July 24, 2006

Dear Ms. Yeaker-Daunis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062107

510(k) No.

Indications For Use

Device Name: SecurView DX

The Hologic SecurView DX device is intended for selection, display, manipulation, filming and media interchange of multi-modality images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or similar interface standards.

The device used with FDA cleared monitors may be used by a trained physician for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images for screening and diagnostic mammography, as well as any other DICOM multi-modality image.

The SecurView DX is typically used by trained professionals, including, but not limited to physicians, radiologists, nurses, medical technicians and assistants.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
21 CFR 801.109

OR

Over-the-Counter Use

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number *K062107*

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